



Shaklee Corporation

9943 '03 APR -4 A9 :22

April 3, 2003

Documents Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket # 02N-0276, Registration of Facilities;  
Implementation of the Bioterrorism Act of 2002

Shaklee Corporation ("Shaklee") is a direct selling company that develops and markets a variety of nutritional supplement and food products through a network of hundreds of thousands of independent distributors throughout the United States who operate home-based business selling Shaklee products. Shaklee submits these comments on the proposed regulations to implement the registration requirement of the Bioterrorism Act of 2002 in order to address the potential impact of these requirements on its distributors as well as the millions of other individuals who participate in direct selling businesses selling pre-packaged nutritional products.

The proposed regulations as currently drafted could be interpreted as requiring individuals who sell pre-packaged nutritional products through direct selling organizations to register with FDA as food facilities. Such a result was not intended by the Bioterrorism Act, is not necessary to accomplish the goals of the Act, and would pose a considerable burden on the millions of individuals who have home-based businesses selling vitamins and other nutritional products.

#### I. The Structure of Direct Selling Companies

Direct selling is a popular model for distributing nutritional supplements. Unlike traditional retailing where products are sold to the general public through retail outlets, in a direct selling business products are marketed through networks of individuals, which fosters a personal relationship with the customer. Many of those engaged in direct selling of nutritional products are in the business part time. For seniors, stay-at-home parents, and others, direct selling businesses provide the opportunity to work a few hours on a flexible schedule, giving them a modest – but often very important – additional source of income.

There are numerous variations of the direct selling model, but the structure of Shaklee's direct selling business is not uncommon. Shaklee independent distributors use their network of personal contacts to develop a customer base. Most of these customers sign up as Shaklee members, entitling them to discounts on product purchases. Many Shaklee independent

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distributors not only sell product to consumers, but recruit new distributors into the Shaklee system. They assist these new distributors with the development and growth of their businesses.

Shaklee develops and manufactures the products and provides marketing material to support the business of the independent distributors. Most Shaklee distributors carry inventories of product which they then sell to end customers. Additionally, many distributors sell inventoried product to other distributors to fulfill customer orders. In some cases, Shaklee ships products directly to the end customer.

The distribution system is a closed system. Shaklee product flows from Shaklee through its independent distributors to customers. All of the independent distributors are under contract with Shaklee. Distributors are not authorized to sell Shaklee product outside this system (e.g. to a retail store). Shaklee maintains contact information for each distributor and for all customers who are Shaklee members, and Shaklee has a variety of mechanisms in place to communicate with the distributor and member network.

## II. Potential Impact of the Proposed Regulations on Shaklee Distributors

Shaklee believes that its independent distributors – and the distributors for other direct selling companies in the food and nutritional supplement market – should be exempt from the registration requirement for food facilities. We are concerned that the current draft of the regulation does not make that sufficiently clear.

Under proposed section 1.226(c) “retail facilities” are exempted from the registration requirement, as required by section 305 of the Bioterrorism Act. “Retail facility,” a term not defined in the Act, is defined in the proposed regulations as “a facility that sells food products directly to consumers only.”

In the proposed definitions, it appears reasonably clear that a home may be considered a facility and that, consequently, a home-based business selling food and nutritional supplements would be a “retail facility” as long as it sells only to consumers. This would exempt some Shaklee distributors from registration.

As discussed above, however, many Shaklee independent distributors – like many distributors in the industry – sell product not only to consumers but also to other independent distributors in their network to support each others’ businesses and enable them to fulfill customer orders. Therefore, qualifying the definition of retail facility with the phrase “to consumers only” would have a significant impact on the direct selling industry. Under the proposed regulations, many distributors in direct selling networks would be excluded from the exemption for retail facilities and would be required to register as food facilities.

This result is not required either by the text of the statute or to support the purposes for which the statute was based, and would place a significant burden on hundreds of thousands of individuals.

There is nothing in the Bioterrorism Act that mandates that retail food establishments be strictly limited to those that sell "only to consumers." It would be a reasonable interpretation of the Bioterrorism Act to permit individuals in a direct selling organization to transfer inventory amongst themselves without thereby disqualifying themselves from the registration exemption.

Moreover, such an interpretation would fully support the purposes of the Bioterrorism Act without overly burdening hundreds of thousands of small, home-based businesses. As FDA notes, the registration program is required because, "[i]n the event of an actual or suspected contamination of food . . . [t]he suspect food must be traced backward and forward through the distribution chain, both to protect consumers and to find the source and cause of the event." 68 Fed. Reg. 5378, 5387 (February 3, 2003). Unlike open distribution chains, where it may be difficult or impossible to trace food shipments unless all distributors touching the food are registered with FDA, direct selling distribution chains are closed systems. That allows Shaklee, or any other direct selling company, to contact every one of its distributors quickly and directly in the case of a problem involving suspected food contamination. Indeed, a direct selling company would be able to contact its distributors far more quickly and efficiently than could FDA even if every distributor were registered. Therefore, it is consistent with both the statutory language and purpose to classify distributors in direct selling networks as retail facilities, even if they sell or otherwise transfer some of their inventory to other distributors in the network.

Without such an interpretation, a significant burden would be imposed on the hundreds of thousands of individuals who are active in direct selling of foods and nutritional supplements and who sell products to other distributors in their marketing networks. Many of these individuals are seniors or others who devote a few hours a week to the business to earn some additional money to supplement their other income. For these individuals, the registration requirements could be quite burdensome. Many do not have access to the Internet and may not be able to register electronically. Others may be reluctant to provide the personal information asked of them. In addition, since individuals move more frequently than businesses, the obligation to update the information on file with FDA would fall more heavily on these individuals than on more traditional businesses. We anticipate that the burden of the registration requirement would cause many distributors to quit the business rather than register. Therefore, the registration requirement as proposed would have a significant impact on Shaklee's business as well as the overall nutritional supplement direct selling business.

### III. Proposal

The language and purpose of the Bioterrorism Act can be fully implemented while recognizing that the millions of individual distributors who operate in direct selling networks are retail facilities, regardless of whether they transfer inventory to other distributors in the network. This could be accomplished by revising the definition of "retail facility" in proposed section 1.227(c) (11) by dropping the word "only" from the first sentence so that it would read: "Retail facility means a facility that sells food products directly to consumers." FDA could then clarify, either in the regulation itself, in the preamble, or in a guidance document that a distributor in a direct selling business who sells inventory to another distributor within a closed distribution system does not thereby lose his or her status as a retail facility exempt from the registration requirement. This approach would permit FDA to require registration of large businesses that conduct both retail and wholesale businesses, while recognizing the unique nature of the direct selling industry.

Alternatively, FDA could specifically address the direct selling model in the exemption provisions in proposed section 1.226 by providing that distributors in a direct-selling organization are not required to register with FDA if the direct selling company with which they are associated (i.e. the company that markets and distributes the products into the distribution channel) has registered with FDA.

If distributors in direct selling businesses are required to register, the burden of registration should be eased by limiting the mandatory information to only that information required by the Bioterrorism Act. The Act requires only that the name and address of the facility be submitted as part of the registration process. In contrast, the proposed regulations would require a facility to provide additional information, including a telephone number, a fax number, and e-mail address for the facility; name and address of any parent company; and emergency contact information, including a name, office phone, home phone, cell phone, and e-mail address.

For an individual operating a home-based direct selling business, this information is highly personal. Moreover, it is unclear whether the provision in the statute that protects registration information from disclosure under the Freedom of Information Act would sufficiently protect the personal information that individuals in direct selling businesses would be required to submit. Therefore, if such individuals are required to register under these regulations, the information sought under the regulation that is not required by statute should be optional rather than mandatory.

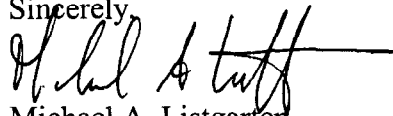
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Shaklee supports this important initiative to safeguard the nation's food supply, but believes it is important to tailor the regulations to maximize their effectiveness while minimizing their

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impact on the millions of individuals engaged in direct selling of food and nutritional products. The draft regulations should be amended to clarify that these individuals are retail facilities that are exempt from the registration requirement.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael A. Listgarten", with a long horizontal flourish extending to the right.

Michael A. Listgarten  
Senior Counsel  
Shaklee Corporation